

|                          |                             |                  |
|--------------------------|-----------------------------|------------------|
| <b>Interview Summary</b> | Application No.             | Applicant(s)     |
|                          | 09/954,987                  | BAUER ET AL.     |
|                          | Examiner<br>Carolyn L Smith | Art Unit<br>1631 |

All participants (applicant, applicant's representative, PTO personnel):

(1) Carolyn L Smith. (3) \_\_\_\_\_.

(2) Alan Steele. (4) \_\_\_\_\_.

Date of Interview: 13 May 2003.

Type: a) Telephonic b) Video Conference  
c) Personal [copy given to: 1) applicant 2) applicant's representative]

Exhibit shown or demonstration conducted: d) Yes e) No.  
If Yes, brief description: \_\_\_\_\_.

Claim(s) discussed: 1-22, 26, 40, 44, 62, 80, 98, 114 and 120.

Identification of prior art discussed: N/A.

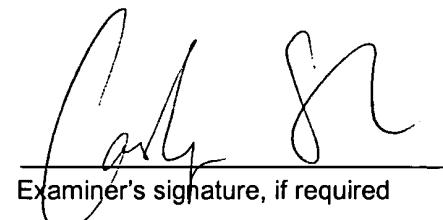
Agreement with respect to the claims f) was reached. g) was not reached. h) N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Attorney was told Applicants can elect any nucleic acid sequence prior to examination. Attorney was told claim 5 will be examined in context with its dependent claim 13.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.



Examiner's signature, if required

## Summary of Record of Interview Requirements

### Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

### Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

#### 37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

### Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

**DETAILED ACTION**

Applicants' election of Group I (claims 1-4, 13-22, and 40), election of Specie C (a TLR which is TLR 9), and sequence election (hTLR9-CXXCm, a full-length human TLR9 modified to include sequence encoding SEQ ID NO: 147) disclosed on pages 1-2 in Paper No. 22, filed 5/15/03, are acknowledged. Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 5-12, 26, 44, 62, 80, 98, 114, and 120 are withdrawn from consideration as being drawn to non-elected Groups. Claims 2-4 are withdrawn from consideration as being drawn to non-elected sequences. Claims 16, 20, 22, and 40 are withdrawn from consideration as being drawn to non-elected species.

As stated in an interview on 5/13/03, Examiner stated the Applicants are allowed to elect any sequence for the sequence election requirement prior to examination. Applicants stated in Paper No. 22, filed 5/15/03, that the Examiner agreed to include examination of claim 5 upon election of Group I, which is not true. It appears the Applicants misunderstood the Examiner in that claim 5 will be examined in the context of its dependent claim 13, but not as an independent claim as it is drawn to a non-elected Group.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title is directed to a process for high throughput screening of CpG-based immuno-agonist/antagonist, whereas in contrast the elected claim is specifically directed to nucleic acids.

Corrected drawings, filed 2/19/03, are approved by the draftsperson.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821 (a)(1) and (a)(2). See for example, Figure 14. However, this application fails to comply with the requirements of 37 CFR § 1.821 through 1.825, because it lacks SEQ ID Nos cited along with each sequence in the Figures. Applicants are also reminded that SEQ ID Nos are not required in Figures per se, however, the corresponding SEQ ID Nos then are required in the Brief Description of the Drawings section in the specification. Applicant(s) are required to submit a new computer readable form sequence listing, a paper copy, or CD-ROM for the specification, statements under 37 CFR § 1.821 (f) and (g), if there is a need to list additional sequences in the sequence listing. Applicant(s) are given the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office Action.

Claims herein under examination are 1, 13-15, 17-19, and 21.

### *Specification*

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, such as on page 29, lines 27 and 28. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The disclosure is objected to because of the following informalities: “fouth” is misspelled on page 9, line 6. Correction of these and any other spelling or grammatical mistakes is requested.

***Claim Objections***

Claims 1, 13, 14, 15, 17, 18, 19, and 21 are objected to due to the inclusion of subject matter which has been non-elected due to a restriction requirement and therefore withdrawn from consideration. The non-elected subject matter in claims 1, 13, 14, 15, 17, 18, 19, and 21 is summarized as follows: Sequence hTLR9-CXXCm was elected and this sequence contains a murine sequence fragment which includes nucleotides 844-861 of SEQ ID NO: 1, nucleotides 805-822 of SEQ ID NO: 2, and encodes amino acid residues 269-274 of SEQ ID NO: 3, but not the entire full-length sequences of SEQ ID NO: 1 and 3 which are encompassed in claim 1. The subject matter from which claim 13 depends (in withdrawn claim 5) also encompasses more amino acid residues than the elected residues 269-274 which are encoded by the elected nucleic acid sequence. Correction is suggested by stating only the nucleotides and amino acid residues that are part of the elected invention. Claims 14-15, 17-19, and 21 are also objected to due to their direct or indirect dependency from claims 1 and 13.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**LACK OF WRITTEN DESCRIPTION**

Claims 1, 13-15, 17-19, and 21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time of the invention was filed, had possession of the claimed invention.

Applicants elected sequence hTLR9-CXXCm, which is encompassed in SEQ ID NO: 4 except for 18 nucleotides which are modified with a murine fragment as seen in SEQ ID NO: 141. The specification discloses SEQ ID NO: 4 which is an hTLR9 sequence as well as a murine fragment as seen in SEQ ID NO: 141. The specification also discloses SEQ ID NO: 1 and 2 (and encoded in SEQ ID NO: 3) which contain murine fragments found and encoded in the elected sequence, hTLR9-CXXCm. SEQ ID NO: 1, 2, 3, 4, and 141 and their full complements meet the written description provisions of 35 U.S.C. 112, first paragraph. However, claims 1, 13-15, 17-19, and 21 are directed to encompass a sequence that is not exactly listed in the specification which does not meet the written description provision of 35 U.S.C. 112, first paragraph. Claims 1 and 13 encompass complements and sequences which hybridize to various SEQ ID NOs as well as fragments which do not meet the written description provision of 35 U.S.C. 112, first paragraph. Due to the open claim wording of "comprises", "comprising", and "having" in claims 1, 14, and 18, and the undefined wording of "the isolated nucleic acid molecule" in claims 14, and 18, these claims are directed to encompass gene sequences that do not meet the written description provision of 35 U.S.C. 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by these claims.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons

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of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO: 1, 2, 3, 4, and 141, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only SEQ ID NO: 1, 2, 3, 4 and 141 but not the full breadth of the claims 1, 13-15, 17-19, and 21 meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

#### ***Claims Rejected Under 35 U.S.C. § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 13-15, 17-19, and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claims 1, 13, 17, and 21 are vague and indefinite due to the unclarity of citing an abbreviation, such as TLR and TIR. Correction is suggested by amending in of the full name in parentheses. Claims 14-15 and 18-19 are also rejected due to their direct or indirect dependency from claims 1 and 13.

Claim 1 recites the phrase “nucleic acid molecules which hybridize under stringent conditions” which is vague and indefinite. It is unclear which criteria the applicants regard as stringent conditions (i.e. buffers, pH of buffer, etc.) or whether low, medium, or high stringency is meant. Applicants can resolve this issue by particularly pointing out the stringent conditions that are intended to allow the polynucleotide to hybridize. Clarification of the metes and bounds of the instant claims is required. Claims 14, 15, and 17 are also rejected due to their direct or indirect dependency from claim 1.

Claim 1 recites the phrase “complements of (a) and (b)” which is vague and indefinite. The claim does not adequately define the phrase which could mean the complementarity is 100% similarity and of the same length of the claimed sequence, or 90% similarity and only a fragment of the claimed sequence, or any other scenario. Appropriate definition of the degree of complementarity to the claimed sequences is required. Claims 14-15, and 17 are also rejected due to their direct or indirect dependency from claim 1.

Claim 18 recites the phrase “comprising the isolated nucleic acid molecule” (claim 18) which is vague and indefinite. It is unclear if the nucleic acid molecule is referring to the entire nucleotide sequence “of claim 13” or just a fragment of the sequence. Clarification of the metes and bounds of the claim via clearer claim wording is requested. Claims 19 and 21 also rejected due to their direct or indirect dependency from claim 18.

Claims 17 and 21 recite the phrase “capable of interacting with a TIR domain” which is vague and indefinite. It is unclear what criteria and to what extent these criteria must be met to qualify as being capable of interacting. The term “capable” is a relative term that is not defined by the claim while the specification also does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Clarification of the metes and bounds of this phrase via clearer claim wording is requested.

#### ***Claim Rejections – 35 USC §102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by GenBank (Accession Numbers BE705670, BE412777, AQ984126, and AF245704).

Sequence hTLR9-CXXCm was elected and this sequence contains a murine sequence fragment which includes nucleotides 844-861 of SEQ ID NO: 1 and encodes amino acid residues

269-274 of SEQ ID NO: 3, but not the entire full-length sequences of SEQ ID NO: 1, 2, and 3.

Due to the unclarity of the claim wording of “complements of” in claim 1, which encompasses fragments and full-length sequences, GenBank discloses sequences (BE705670, BE412777, and AQ984126) which contain nucleotides at positions 531-536, 99-104, and 368-373, respectively, which match the fragment “GGCCAA” which is found in SEQ ID NO: 1. GenBank also discloses a sequence (AF245704) which contains nucleotides at positions 145-948 and 967-3240 which match fragments 1-804 and 823-3096 of elected sequence hTLR9-CXXCm.

Thus, GenBank (Accession Numbers BE705670, BE412777, AQ984126, and AF245704) anticipates the limitations in claim 1.

Claims 1 and 13 are rejected under 35 U.S.C. 102(a) as being anticipated by GenBank (Accession Number AL356815, page 4 of Sequence Match listing).

Sequence hTLR9-CXXCm was elected and this sequence contains a murine sequence fragment which includes nucleotides 844-861 of SEQ ID NO: 1 and encodes amino acid residues 269-274 of SEQ ID NO: 3, but not the entire full-length sequences of SEQ ID NO: 1, 2, and 3. Due to the unclarity of the claim wording of “complements of” in claim 1, which encompasses fragments and full-length sequences, GenBank discloses a nucleic acid sequence (AL356815) which contains a fragment that encodes amino acid residues, GQKS (page 21, line 21) as found in SEQ ID NO: 3 (residues 269-272). AL356815 discloses a fragment (residues 330-333, page 24) which is identical to the nucleic acid fragment “GGCC” which is found in SEQ ID NO: 1.

Thus, GenBank (Accession Number AL356815) anticipate the limitations in claim 1.

***Conclusion***

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The examiner can normally be reached Monday through Friday from 8 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

July 15, 2003

*Ardin H. Marschel*  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER